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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/746,635	11/13/96	MURTHY	96/001,141

HM12/0328

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EXAMINER	
GABEL, G	

ART UNIT	PAPER NUMBER
1641	36

DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/746,635	MURTHY ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *23 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 2/23/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/746,635 is acceptable and a CPA has been established. Currently, claim 20 is pending and under examination. An action on the CPA follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsson et al. (Journal of Applied Biochemistry, 5:437-445 (1983)) for reason of record.

Response to Arguments

3. A) Applicants argue that although Olsson found correlation between hemoglobin and adenylate kinase, the ratio of hemoglobin to extracellular adenylate kinase between red blood cell concentrates depicted were significantly different. Applicants point to Figure 6A and 6B, pages 442 and 445 for reference.

In response, the accumulation of adenylate kinase in Figures 6A, 6B, and 6C in the Olsson reference are effected by their difference in hematocrit (packed red cell) levels so that elevated hematocrit as in Figure 6A and 6B commands elevated accumulation of adenylate kinase activity due to increased hemoglobin leakage as compared to one with a lower hematocrit level (whole blood). Nevertheless, the ratio between adenylate kinase and hemoglobin has remained relatively constant as per Olsson whose correlation results appear to overlap with the values obtained by the applicants in the instant invention.

B) Further, applicants argue that Olsson neither teaches nor suggests using adenylate kinase activity for diagnosing erythrocyte hemolysis in vivo and provides no evidence to support that erythrocyte adenylate kinase activity actually correlates with hemolysis in vivo.

In response, while the instant invention is drawn to determining adenylate kinase activity as effected by in vivo or in situ hemolysis in patients due to physiologic or pathologic causes, Olsson's study is drawn to detecting adenylate kinase activity in stored blood cells as effected by leakage of adenylate kinase from aging of erythrocytes. A person with ordinary skill in the art at the time would have appreciated the correlation between hemolysis and erythrocyte adenylate kinase suggested by Olsson as emphasized by the parallel between hemoglobin (a known indicator of hemolysis) and erythrocyte adenylate kinase. Indeed, Olsson teaches determination of erythrocytic adenylate kinase as a measure of enzymatic activity and further teaches the critical correlation between erythrocyte adenylate kinase and hemolysis regardless of the fact that the phenomenon of hemolysis occurred in vivo or in vitro. The criticality in both methods is in the measuring of enzyme activity in adenylate kinase as it correlates to hemolysis, i.e. occurrence of "free" hemoglobin outside of an erythrocytic cell; not whether such occurrence takes place in vivo or in vitro.

C) Applicant further argues that Olsen provides no teaching or suggestion that the presence of at least about 20 U/L erythrocyte kinase activity is indicative of erythrocyte hemolysis in a subject.

In response, minimum diagnostic values acquired in detection or determination methods of analyte activity have been substantially shown by the prior art reference to be achieved using maximization or optimization procedures. "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges (or values) by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). The "discovery of an optimum value in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitation recited in instant claim 20 is for any particular purpose, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range of the adenylate kinase activity determination method disclosed by the prior art by normal optimization procedures.

3. Applicant's arguments have been considered but are not deemed persuasive. Claim 20 is not allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
Art 1641
March 23, 2001

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

3/23/01